REMARKS

Support for the amendments

The amendments to claim 45 are supported throughout the application, for example within the claim as previously presented. Thus, the amendments do not constitute new matter.

Claim rejections under 35 USC 112 first paragraph

Claims 6, 9, and 19-53 were rejected under 35 U.S.C. 112, first paragraph as containing subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventors had possession of the claimed invention at the time the application was filed. Specifically, the patent office asserted that the claims encompass a genus of NPHS1 proteins or nucleic acids which are different that those disclosed in the specification. The patent office, citing the CAFC decision *The Regents of the University of California v. Eli Lilly and Co.*, further asserted that the definition of NPHS1 in the claims completely lacks any specific structure, sequence, or even domains, so that those of skill in the art would not understand that the Applicants had possession of the claimed invention. The Applicants traverse this rejection.

Claims 6 and 9 have been cancelled. All of the remaining claims recite that the methods of the invention involve detecting mutations in either exon 2 or exon 26 of the NPHS1 gene encoded by SEQ ID NO:1. Thus, the currently pending claims all provide a common element or attribute of the sequence (SEQ ID NO:1) that is being analyzed in the methods of the invention, and further recites specific domains of the sequence (ie: exon 2 and 26) that are being analyzed for mutations.

The Written Description Guidelines state that the written description requirement for a claimed genus may be satisfied by description of a sufficient number of representative species, and that this requirement can be satisfied by functional characteristics coupled with a known or disclosed correlation between function and structure. The purpose of sufficient written description is to reasonably convey to one skilled in the relevant art that the inventors, at the time of the invention, had possession of the claimed invention. The claimed invention encompasses methods of detecting a

mutation in specific exons (exons 2 or 26) of the NPHS1 gene (encoded by SEQ ID NO:1) that the Applicants have correlated with a basement membrane disease, congenital nephritic syndrome of the Finnish Type, or for determining an individual's risk of the disease by identifying mutations in the same exons (2 or 26) of the NPHS1 gene encoded by SEQ ID NO:1 that have been associated with mutations leading to the disease. It would be clear to those of skill in the art that the Applicants were in possession of the invention at the time of filing, since the Applicants have provided the first description of the NPHS1 gene, described representative species of NPHS1 mutations, and have coupled the functional characteristic of mutations present in exon 2 or 26 with a correlation to basement membrane disease, such as congenital nephritic syndrome of the Finnish Type. Thus, the presently pending claims fulfill the written description requirement of 35 USC 112. This is further supported by the recent case Capon v. Eshar (Fed. Cir. No. 03-1480, August 12, 2005), which stated "[I]t is not necessary that every permutation within a generally operable invention be effective in order for an inventor to obtain a generic claim, provided that the effect is sufficiently demonstrated to characterize a generic invention."

Furthermore, claim 49 simply recites a method for detecting mutations in exons 2 and/or 26 of the NPHS1 gene. The present invention discloses a novel isolated gene, as well as clinically significant mutations in the gene within exons 2 and 26. Thus, the Applicants have disclosed methods for identifying mutations in the NPHS1 gene and have demonstrated that some such mutations have clinical significance. Those of skill in the art would thus clearly understand that the applicants had possession of techniques for identifying mutations in the NPHS1 gene within these exons. The Applicants respectfully remind the patent office that they are not attempting to claim the mutated nucleic acids themselves; instead, they are claiming a method for identifying such mutations. Based on the teachings of the present invention, those of skill in the art are well aware that the Applicants have identified exons 2 and 26 as locations in the NPHS1 gene that can be mutated with clinically significant consequences. Thus, the Applicants have disclosed methods for identifying those as well as other mutations within these exons that may also have clinical significance, as recited in pending claim 49 and its

dependent claims. Those of skill in the art would be well aware that the Applicants had possession of the claimed invention.

Based on the above, the Applicants respectfully request reconsideration and withdrawal of the rejection.

CONCLUSIONS

Applicant respectfully contends that the instant application is in condition for allowance in view of the claim amendments and arguments presented above, and respectfully requests it be allowed. If the Examiner believes that a telephone or personal interview would expedite prosecution of the instant application, the Examiner is respectfully invited to call the undersigned attorney at (312) 913-2106.

Respectfully submitted,
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